Contains Nonbinding Recommendations

Instructions for Completing Form FDA 3666
OMB No. 0910-0583; Expiration Date: 08/31/2024
Department of Health and Human Services
Food and Drug Administration
Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)

I. General Instructions

- Form FDA 3666 is intended to help you assemble and transmit a New Protein Consultation (NPC) to FDA.
- Completion of this form alone does not constitute a complete submission. A complete submission also includes the items listed in Part VI of Form 3666.
- To prepare your submission in electronic format, you should download a NPC Submission Roadmap, which has a foldering structure, and place your files in the applicable folders (see Appendix 15 in Internet Resource #1 for a link to the downloadable foldering structure).
- To transmit your submission:
    - You may upload the completed NPC foldering structure to the Electronic Submission Gateway (ESG). For information on using the ESG, see Internet Resource #2 in Part III of these instructions; or
    - You may send the completed submission, either in hard copy (including the form and all attachments) or in electronic format on physical media, to: Office of Food Additive Safety, HFS-200, 5100 Paint Branch Parkway, College Park, MD 20740-3835.
- Additional information about NPCs is available on FDA's Internet Site (see Internet Resource #1 in Part III of these instructions).

II. Specific Instructions for Each Part of the Form

1. Part I – Introductory Information About the Submission

In Part I, you tell us:

- Whether your submission is a new submission, or an amendment or supplement to a previously established NPC;
- Whether you have determined that all files provided in an electronic transmission are free of computer viruses;
- The date of your most recent meeting (if any) with FDA before transmitting a new submission; and

- The date of any correspondence, sent to you by FDA, relevant to an amendment or supplement you are transmitting;

2. Part II – Information About the Person Responsible for the Submission

In Part II, you identify:

- The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the submission;
- The contact person within any partnership, corporation, association, or other legal entity; and
- Any agent or attorney who is authorized to act on behalf of the person responsible for the submission. If the agent or attorney is the preferred contact person, write "See agent or attorney" in the box for "Name of Contact Person."

3. Part III - General Administrative Information

In Part III, you tell us:

- The title of your submission;
- The format of your submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (i.e., ESG or transmission on physical media such as CD-ROM or DVD);
- Whether you are referring us to information already in our files;
- Whether you have designated in your submission any information that you view as trade secret or as confidential commercial or financial information (see 21 CFR part 20 and Internet Resource #1 in Part III of these instructions); and
- Whether you have attached a redacted copy of some or all of the submission. A redacted copy is a copy modified to remove data or information that you view as trade secret or as confidential commercial or financial information.

4. Part IV –Information About the New Protein

In Part IV, you:

- Tell us the name of the new protein
- Have an option to provide any registry designations for the new protein ; and
- Describe the purpose or intended technical effect of the new protein.

5. Part V –Information About Genetic Material

In Part V, you provide information about the introduced genetic material (including identity and source).

6. Part VI – Scientific Evaluation of the Food Safety of the New Protein

Part VI provides a checklist for those elements of a NPC that do not get completed directly on Form 3666:

- Whether there is a history of safe use in food or feed
- Whether you have included an assessment of the amino acid similarity between the new protein and known allergens and toxins;
- Whether you have included information about the overall stability of the protein, and the resistance of the protein to enzymatic degradation using appropriate *in vitro* assays; and
- Whether you included any other information, you want us to consider in evaluating your NPC.

7. Part VII – Signature

In Part VII, you print or type the name and title of the responsible official (or agent or attorney) who is signing the submission, and sign and date the form.

8. Part VIII - List of Attachments

In Part VIII, you should list all attachments you include in your submission (For information about downloading and organizing the attachments in your electronic submission please refer to Appendix 15). If you are completing the form by electronic means use the "Insert" button to browse for a file name that you want to insert in the box for "Attachment Name." Use the "Clear" button if you want to remove or replace the "Attachment Name" you inserted. For paper submissions, you should number consecutively the pages within the attachments and enter the inclusive page numbers of each portion of the complete paper submission.

III. FDA Internet Resources

The following resources are available on FDA's Internet site.

1. Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper format to Office of Food Additive Safety. This guidance document includes a list of, and hyperlinks to, guidance documents associated with the preparation of NPCs.
2. Electronic Submission Gateway